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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,077	06/01/2005	David Duncan Heath	JAMES68.008APC	8641

20995 7590 11/24/2009

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EXAMINER	
BERRIOS, JENNIFER A	

ART UNIT	PAPER NUMBER
1619	

NOTIFICATION DATE	DELIVERY MODE
11/24/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/517,077	HEATH, DAVID DUNCAN	
	Examiner	Art Unit	
	Jennifer A. Berríos	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the reply filed on 8/20/2009.

Currently claims 1-10 and 31 are pending examination.

Response to Arguments

6. Applicant's arguments, filed 8/20/2009, with respect to the rejection(s) of claim(s) 1-10 and 31 under 35 USC 103(a)(have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made below.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claim 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashmi et al (WO 01/07079, pub date: 2/1/2001), Tamura et al (Immunology (1975) Vol.

28, No. 5, pg 909-924) and Folds et al (Journal of Clinical Microbiology, Aug 1983, Vol. 18, pg 321-326).

Regarding claims 1-3 and 5-9, Hashmi teaches a vaccine formulation providing for the extended release of antigenic material over time. The release profile of the different embodiments can be varied, allowing a single administration to establish active immunity in an animal (Abstract). The antigenic material will be released from the carrier system over a period of time after introduction of the vaccine into the subject (Pg 3, lines 25-26). The at least one antigenic substance will be dispersed in a pharmacologically acceptable carrier (Pg 20, claim 1). Hashmi contemplates periodically supplementing a relatively constant rate with burst of higher release, used to trigger the immune system to remain highly active over time (Pg 10, lines 7-10). It is also suggested that the shape of the device can be chosen to affect both the initial release rates and the effect of any tailing off thereof (Pg 12, lines 23-25). .

A further variation is for the device to have multiple layers, or graduated layers. This allows for differing release rate profiles merely by adding layers of different solubility and/or release rates, or containing different concentrations of active material. (Pg 12, lines 26-29) Hashmi further teaches that the vaccine delay can exceed 24hrs and also 5days (Pg 21, claim 15-16).

While Hashimi teaches increasing release profiles and varying concentrations of pharmaceutical agents in a single vaccine administration, Hashimi fails to teach increasing dose.

Tamura teaches cellular and humoral immune responses in mice and teaches that the anti TNP antibody production was maximally enhanced by presensitization with a low dose of SRBC and gradually abolished with higher does of SRBC for pre sensitizations. In the latter case, anti SRBC antibody production was increased with increasing doses of SRBC (Abs).

Folds teaches purified Rickettsia rickettsii vaccine evaluated in guinea pig models. Guinea pigs were partially protected by the vaccine when challenged with virulent, viable rickettsiae. However, greater protection was observed when higher doses of vaccine were given and when frequent booster injections were administered (Abs).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Hashimi, Tamura and Folds to increase doses of a pharmaceutical agent in a single, administratable composition. One of skill in the art would have been motivated to utilize the vaccine formulation device of Hashimi, having different release rate and concentration profiles, to create a formulation with increasing doses to ensure greater protection and higher antibody production. Further, one of ordinary skill in the art at the time the invention was made would have been motivated to increase dosages, taught by Tamura and Folds, in the single formulation of Hashimi, to eliminate multiple administrations, resulting in greater patient compliance and health care efficiency. (It's always required to have one motivation, but multiple motivations renders an invention that much more obvious, especially if the motivation is based on fundamental general desires, i.e. decreased cost and increased

efficiency). Finally one of skill in the art would have had a (there is a legal president for verb tense here for this analysis) reasonable expectation of success for combining increased doses of Tamura and Folds in the single vaccine formulation of Hashimi because Hashimi teaches increasing release rates and varying concentrations of pharmaceutical agents in a layered configuration within a single composition, see pertinent page and line numbers) and Tamura/Folds teach increased immunogenicity and protection with vaccine formulations administered with increasing doses.

4. Claim 10 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashmi et al (WO 01/07079, pub date: 2/1/2001), Tamura et al (Immunology (1975) Vol. 28, No. 5, pg 909-924) and Folds et al (Journal of Clinical Microbiology, Aug 1983, Vol. 18, pg 321-326), as applied to claims 1-9 above, and further in view of Sako et al (WO 94/06414, pub. date: 3/31/1994)

For ease of examination, the Examiner relied upon US Patent 6,436,441 as an equivalent English translation of the Japanese WO 94/06414 publication. All citations henceforth to Sako are locations in the US Patent.

Sako teaches a hydrogel-type sustained release preparation comprising at least one drug. Fig. 10 demonstrates different plasma drug concentrations having a progressively increased dosage around 2 hrs.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Hashimi/Tamura/Folds and Sako. While Hashimi, Tamura, Folds and Sako do not specifically teach doubling the dose or

the specific incremental concentrations of agents instantly recited in claims 4, 10 and 31, manipulation of relative amounts of formulation components resulting in differences in concentration will not support the patentability of subject matter encompassed by the prior art, unless there is evidence indicating that such concentration data is critical. "[W]here the general conditions of a claim are disclosed in prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The adjustment of particular conventional working conditions as well as affecting the desired therapeutic effect, is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Accordingly, this type of modification is no more than an effort to optimize results. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Berríos whose telephone number is (571)270-7679. The examiner can normally be reached on Monday-Thursday: 7:00am-4:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 270-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JB

/SUE LIU/
Primary Examiner, Art Unit 1639